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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|----------------------|------------------|
| 10/754,844 | 01/08/2004 | John L. Sommer | P-10537.04 | 1079 |
| 27581 | 7590 | 05/19/2006 | EXAMINER | |
| MEDTRONIC, INC. 710 MEDTRONIC PARK MINNEAPOLIS, MN 55432-9924 | | | LAYNO, CARL HERNANDZ | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3766 | |

DATE MAILED: 05/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/754,844

Applicant(s)

SOMMER ET AL.

Examiner

Carl H. Layno

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 13 is/are rejected.
- 7) ☒ Claim(s) 3-12 and 14-16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 January 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1/8/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for priority as a Continuation-In-Part of U.S Application Serial No. 10/262,046, filed on October 2, 2002.

Information Disclosure Statement

2. Acknowledgment is made of applicant's Information Disclosure Statement (PTO-1449), which was received by the Office on January 8, 2004.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "electromagnetic imaging or mapping system" of claim 16 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

The drawings are further objected to by the Draftsperson. See attached PTO-948 for comments.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure

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must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Altman et al (US 6,296,630).

The Altman et al (US 6,296,630) patent describes a system discloses a plurality of embodiments involving endocardial drug delivery catheters. Applicant's attention is directed to Fig.1D, which shows that the concept of a helical anchor mechanism **50** in combination with a drug delivery needle **55** is well known "prior art". According to Altman et al, "It should be clear

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that it would be very easy to design needle 55 so that it is not centrally located” (col.10, lines 48-50). In fact, Altman et al describes an embodiment (Fig.4) in which the drug delivery catheter has a “preferred curve shape” **803**.

In regard to claim 13, the tip of drug delivery needle **55** (Fig.1D) of Altman et al appears to be “beveled”.

6. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Altman (US 6,102,887).

The Altman (US 6,102,887) patent describes an implantable cardiac drug delivery system (Figs.8A-8C) reading upon applicant’s claimed features. Specifically, the system includes a catheter 820 (Figs.8A-8C) having a hollow “penetrating needle 865” that communicates through its base to a “drug delivery tube 810[825]” (col.9, lines 27-29) to a proximal port (not shown). The Altman catheter 820 includes two prongs 860,870, which act as fixation elements. According the specification (col.10, lines 23-26) “the needles could be formed of a shape memory material such as nitinol so that once released from the confines o the catheter body 820 they take on the curved shoape shown, or even more drastic curves”.

7. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Lederman (US 2003/0032936 A1).

The Lederman (US 2003/0032936 A1) U.S Patent Application Publication describes a catheter (Fig.3) whose features appear to read upon applicant’s claimed implantable medical lead structure. Specifically, the embodiment of Fig.3 shows an implantable catheter **10** having a

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delivery lumen 14 defining a distal port 16 and a proximal port (not shown), and a guidewire pigtail 42 located near the distal tip of the catheter 10 that performs the function of a “fixation element”. A “fluid delivery device” in the form of a “secondary catheter” 26 for delivering therapeutic drugs is inserted within lumen 14 and exits distal port 16 at an angle of about 75 degrees (p.3, paragraph [0027], lines 1-4). The distal tip of this “secondary catheter”, element 28, appears in Fig.3 as shown having a beveled tip end.

Allowable Subject Matter

8. Claims 3-12 and 14-16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.


The Vachon (US 5,531,780), Altman et al (US 6,086,582), and Osypka (US 5,261,419) patents are cited for their pertinent disclosure of implantable drug delivery catheters having helical fixation mechanisms and drug delivery needles/mechanisms. Unlike, applicant's device, however, there is no teaching for using a “fluid delivery device” having a “pre-formed curve”.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (571) 272-4949. The examiner can normally be reached on 9/4/5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



CARL LAYNO
PRIMARY EXAMINER

CHL
5/15/2006